

### REMARKS

The Office Action of September 30, 2005, has been received and reviewed.

Claims 1-14 are currently pending in the above-referenced application. Of these, claims 1-5 have been withdrawn from consideration, while claims 6-14, which have been considered, stand rejected.

Claims 1-5 have been canceled without prejudice or disclaimer.

New claims 15-40 have been added.

Reconsideration of the above-referenced application is respectfully requested.

### Claim Amendments

Several claim amendments have been presented. Many of the revisions are formal in nature. In addition, the term "said" has been replaced with the more colloquial term "the." Typographical errors have also been corrected. None of these revisions should be construed as limiting the scope of any of claims 6-14.

### Claim Objections

The Office objected to claim 9 because the term "bolus" was misspelled. This typographical error has been corrected. Accordingly, withdrawal of the objection to claim 9 is respectfully requested.

### Rejections under 35 U.S.C. § 102(b)

Claims 6, 8-10, and 12-14 stand rejected under 35 U.S.C. § 102(b) for being directed to subject matter that is allegedly anticipated by the disclosure of U.S. Patent 5,088,981 to Howson et al. (hereinafter "Howson").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Howson describes a system and apparatus for administering drugs. The system of Howson includes a programming unit 13 and a delivery unit 14. *See* FIG. 1; col. 6, lines 22-36. The programming unit 13 includes a computer 16 that, under control of an appropriate program 24, may model a drug, by pharmacokinetic, pharmacodynamic, or dose-response data, that is to be delivered by the delivery unit 14. *See, id.; see also*, col. 7, lines 4-50. Such modeling may be useful in controlling the dosage of the drug to be administered by the delivery unit 14. Col. 7, lines 37-57.

While Howson notes, at col. 7, lines 10-17, that the computer 16 may operate under control of a graphics program, Howson provides few, if any, details as to what, if anything, a graphics program may cause the computer 16 to depict.

It is respectfully submitted that the disclosure of Howson does not anticipate each and every element of any of claims 6-14.

With respect to the subject matter recited in independent claim 6, Howson lacks any express or inherent description that the system thereof includes a drug display monitor “configured to depict” the concentrations of one or more drugs that have been at least indirectly introduced into blood of a subject. In addition, Howson does not expressly or inherently describe that such a depiction may be effected “in real time.” Further, Howson neither teaches or suggests that either a present or future blood concentration of at least one drug may be shown by a drug display monitor of the system disclosed therein. For these reasons, it is respectfully submitted that Howson does not anticipate at least four different elements of independent claim 6, as amended and presented herein.

Each of claims 8-10, 12, and 13 is allowable, among other reasons, for depending directly or indirectly from claim 6, which is allowable.

Claim 13 is additionally allowable since Howson includes no express or inherent description that the programming unit 13 or any other component of the system disclosed therein includes a display generator that produces a display of past, present, and predicted drug site concentration. Again, while Howson notes that the concentrations of a drug in a subject’s blood may be modeled by the disclosed system, Howson lacks any disclosure that the disclosed system may depict past, present, or future concentrations of the drug.

Independent claim 14, as amended and presented herein, recites a system for data representation. The system of independent claim 14 includes, among other things, a display monitor that is configured to depict, graphically and substantially in real-time, a modeled concentration of at least one drug in blood of a subject.

Howson lacks any express or inherent description that the system thereof includes a display monitor that is configured to graphically depict a modeled concentration of at least one drug in blood of a subject. Howson also lacks any express or inherent description that the system thereof depicts a modeled concentration of at least one drug in blood of a subject substantially in real-time. Therefore, Howson does not anticipate each and every element of amended independent claim 14, as would be required to maintain the 35 U.S.C. § 102(b) rejection of that claim.

Withdrawal of the 35 U.S.C. § 102(b) rejections of claims 6, 8-10 and 12-14 is, therefore, respectfully requested.

#### **Rejections under 35 U.S.C. § 103(a)**

Claims 7 and 11 have been rejected under 35 U.S.C. § 103(a) for reciting subject matter that is assertedly unpatentable over teachings from Howson, in view of the subject matter taught in U.S. Patent 5,925,014 to Teeple, Jr. (hereinafter "Teeple").

Claims 7 and 11 are allowable, among other reasons, for depending directly and indirectly, respectively, from claim 6, which is allowable.

#### **Double Patenting Rejections under 35 U.S.C. § 101**

Claims 6-12 and 14 stand provisionally rejected under 35 U.S.C. § 101 for purportedly claiming the same invention as that of claims 6-11, 15, and 19 of copending U.S. Patent Publication US 2003/0156143 A1.

In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice?

. . . Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an

embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.

It is respectfully submitted that claims 6-12 and 14 of the above-referenced application do not recite identical subject matter to that recited in claims 6-11, 15, and 19 of copending U.S. Patent Publication US 2003/0156143 A1. The differences between the claims of the above-referenced application and those of U.S. Patent Publication US 2003/0156143 A1 are evident from an element-by-element comparison. Therefore, it is respectfully submitted that, under 35 U.S.C. § 101, claims 6-12 and 14 are allowable over claims 6-11, 15, and 19 of copending U.S. Patent Publication US 2003/0156143 A1.

Accordingly, it is respectfully requested that the 35 U.S.C. § 101 rejections of claims 6-12 and 14 be withdrawn.

#### **New Claims**

New claims 15-40 have been added.

New claims 15-21 depend directly or indirectly from claim 6 and are allowable, among other reasons, for depending directly or indirectly from claim 6.

New claims 22-34 depend directly or indirectly from claim 14 and are allowable, among other reasons, for depending directly or indirectly from claim 14.

New claim 35 is an independent claim that is directed to a system for modeling a concentration of at least one drug in blood of a subject, which system includes a processing element programmed to model a concentration of at least one drug in blood of a subject over time and an output element for displaying, substantially in real-time, a modeled concentration of the at least one drug in reference to at least one concentration at which the at least one drug will have a desired affect against a known percentage of a population. It is respectfully submitted that Howson does not disclose a system that includes an output element that is configured to display a modeled concentration of at least one drug in blood of an individual substantially in real-time or to display a modeled concentration of the at least one drug in reference to at least one concentration at which the at least one drug will have a desired affect against a known percentage

of a population. Thus, the subject matter recited in new independent claim 25 is allowable over the subject matter disclosed in Howson.

New claims 36-40 depends directly or indirectly from new claim 35 and are each allowable, among other reasons, for depending from claim 35.

None of new claims 15-40 introduces new matter into the above-referenced application.

### CONCLUSION

It is respectfully submitted that each of claims 6-40 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



Brick G. Power  
Registration No. 38,581  
Attorney for Applicants  
TRASKBRITT, PC  
P.O. Box 2550  
Salt Lake City, Utah 84110-2550  
Telephone: 801-532-1922

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